Remarks

Claims 20, 21, 23, 24, 28-39, and 47-53 are currently pending in the application, including independent claims 20, 30, and 48 and withdrawn claims 30-39 and 47. For instance, independent claim 20 is directed to an implantable fixed tissue comprising cross-linked elastin. More specifically, the elastin of the implantable fixed tissue is cross-linked with a phenolic tannin cross-linking agent. Accordingly, the implantable fixed tissue includes a residue of the phenolic tannin cross-linking agent bound to and cross-linking the elastin of the tissue.

Presently presented amendments to the claims include the addition of new claims 48-53. Applicants respectfully submit that new claims 48-53 are fully supported by the specification as filed, for instance at paragraphs [0006] and [0038] of the specification, and present no New Matter to the application.

In the Office Action, claim 24 was objected to under 37 C.F.R. §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant respectfully disagrees.

Claim 20 is directed to a fixed tissue including elastin that is cross-linked with a phenolic tannin cross-linking agent. Claim 24 further limits the cross-linking agent as to type through recitation of the specific phenolic tannin, tannic acid, as the cross-linking agent of the fixed tissue of claim 24. As described in the captioned application (see, e.g., ¶ [0040]), the fixatives of the application can include phenolic tannin fixatives. While tannic acid is one phenolic tannin that can be utilized in one preferred embodiment, the application is clearly not limited to this particular phenolic tannin. The application encompasses other phenolic tannin cross-linking agents, in addition to tannic acid. For instance, other phenolic tannin cross-linking agents specifically disclosed in the application include gallotannins, catechins, flavonoids, and derivatives of these phenolic tannins. Other phenolic tannins as may cross-link elastin according to the disclosure are also encompassed by the pending claims. Applicant respectfully submits that claim 24 is fully compliant with 37 C.F.R. §1.75(c) and requests withdrawal of the objection.

In the Office Action, claims 20-21, 23-24 and 28-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nimni, et al. (U.S. Patent No. 4,378,224) in view of Nimni, et al. (U.S. Patent No. 5,374,539).

Applicants respectfully submit that claims 20-21, 23-24, and 28-29 patentably define over the cited references for at least the reason that even if combined as suggested, the combined references still fail to teach limitations of the claims. For instance, neither Nimni, et al. '224 nor Nimni, et al. '539 disclose or suggest a fixed tissue including the residue of a phenolic tannin cross-linking agent bound to and cross-linking elastin of the fixed tissue.

As correctly pointed out in the Office Action, Nimni, et al. '224 does not teach cross-linking with the claimed phenolic tannins. In addition, Applicants respectfully submit that Nimni, et al. '224 does not teach a tissue including cross-linked elastin.

Nimni, et al. generally discloses treatment of natural tissues with tanning agents such as formaldehyde and glutaraldehyde (col. 1, ll. 17-20). More specifically, Nimni, et al. '224 discloses a cross-linked, modified tissue. To form the disclosed products, a tissue is first cleaned and treated to sequester calcium. Following initial treatment, the tissue is then placed in a solution containing glutaraldehyde to cause partial cross-linking of the collagen (col. 2, ll. 60-68). As is generally known, glutaraldehyde fixation forms covalent cross-links between free amines in collagen. Elastin, in contrast, lacks the free amine groups that provide the cross-link sites for glutaraldehyde. As such, while glutaraldehyde can provide suitable fixation of the collagen in a connective tissue, elastin is not likewise fixed when a tissue containing both elastin and collagen is treated with glutaraldehyde (or formaldehyde). Thus, while Nimni, et al. discloses a tissue that includes collagen cross-linked with a tanning agent such as glutaraldehyde or formaldehyde, the reference simply does not disclose a tissue including phenolic tannin residues bound to and cross-linking the elastin component of a tissue.

Nevertheless, Nimni, et al. '224 was combined with Nimni, et al. '539 in an attempt to render claims 20-21, 23-24, and 28-29 obvious.

Nimni, et al. '539 is directed to a method for preparing a purified collagen network. The method includes subjecting tissue to proteolytic enzymes in the

presence of salt to remove not only the non-helical extensions at either end of a collagen molecule, but also cellular proteins, interfibrillar proteins, glycoproteins, residual serum proteins, and other extraneous material leaving behind the helical region of collagen (col. 3, l. 56 – col. 4, l. 10). Subsequent to the formation of the purified collagen configuration, the fibrillar collagen can be preserved through crosslinking the network with tanning reagents, and specifically, with glutaraldehyde. Thus, and similar to Nimni, et al. '224, Nimni, et al. '539 does not disclose an implantable tissue including phenolic tannin residues bound to and cross-linking elastin of the tissue.

Neither Nimni, et al. '224 nor Nimni, et al. '539 disclose a fixed tissue including cross-linked elastin. In addition, neither Nimni, et al. '224, nor Nimni, et al. '539 disclose or suggest a fixed tissue including the residue of a phenolic tannin bound to and cross-linking elastin of the tissue.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. Applicants respectfully submit that in the present instance, the combined references fail to disclose or suggest an implantable tissue including phenolic tannin residues bound to and cross-linking elastin of the implantable tissue.

Nimni, et al. '224 and Nimni, et al. '539 fail to disclose or suggest additional limitations of the claims as well. For instance, even were Nimni, et al. '224 and Nimni, et al. '539 to be combined as suggested in the Office Action, the combined references would still fail to disclose or suggest an implantable tissue including a residue of a phenolic tannin cross-linking agent bound to and crosslinking elastin of the tissue and also including a residue of a glutaraldehyde cross-linking agent bound to and cross-linking collagen of the fixed tissue as is found in claim 24.

In addition, even if combined, the combined references would still fail to disclose or suggest an implantable fixed tissue including both a residue of a phenolic tannin

cross-linking agent bound to and cross-linking elastin of the fixed tissue, and also including a residue of an aldehyde cross-linking agent bound to and cross-linking collagen of the fixed tissue, as is found in claim 48.

For at least these reasons, Applicants respectfully submit that claims 20-21, 23-24, and 28-29 patentably define over the cited references and request withdrawal of the rejection.

In the Office Action, claims 20-21, 23-24, and 28 were rejected under 35 U.S.C. §103(a) as obvious over Adkisson (U.S. Patent No. 6,645,764) in view of Asculai, et al. (U.S. Patent 6,444,222).

Applicants respectfully submit that claims 20-21, 23-24, and 28 patentably define over the cited reference for at least the reason that even if combined, the combined references still fail to disclose or suggest certain limitations of the claims. For example, even if combined Adkisson and Asculai, et al. together still fail to disclose or suggest an implantable fixed tissue including cross-linked elastin and a residue of a phenolic tannin cross-linking agent bound to and cross-linking elastin of the tissue, as is found in claim 20.

As correctly noted in the Office Action, Adkisson is silent as to the tissue containing elastin. Specifically, Adkisson does not disclose or suggest an implantable tissue including cross-linked elastin.

Nevertheless, Adkisson was combined with Asculai, et al. in an attempt to render claims 20-21, 23-14, and 28 obvious.

Similar to Adkisson, however, Asculai, et al. also fails to disclose an implantable tissue including cross-linked elastin.

Asculai, et al. discloses a reinforced matrix membrane containing one or more scaffold-forming proteins (Abstract). More specifically, the matrix is a collagen matrix (col. 5, ll. 8-9). The collagen matrix is described as either a reconstituted collagen matrix (i.e., cartilage tissue treated to obtain the collagen in its virtually non-cross-linked form that is then crosslinked to reestablish collagen crosslinks) (col. 5, ll. 36-53) or the collagen matrix can be formed from recombinantly produced Type II collagen

(col. 60-65). Commercially available collagen matrixes are also disclosed (col. 5, l. 66 – col. 6, l. 18). The collagen matrix can be cross-linked (col. 6, ll. 19-43).

To form the reinforced collagen matrices, the cross-linked collagen matrices are incubated with different quantities of a scaffold forming protein such as elastin (col. 5, ll. 8-9; col. 5, ll. 54-59; col. 7, ll. 44-67; Examples 3-5). Hence, the reinforced matrix membranes disclosed by Asculai, et al. include a cross-linked collagen matrix and a scaffold forming protein that has been loaded into the cross-linked matrix via incubation.

Even if combined, the combination of Adkisson and Asculai, et al. does not disclose or suggest an implantable fixed tissue including cross-linked elastin. In addition, the combination of Adkisson and Asculai, et al. does not disclose or suggest a fixed tissue including the residue of a phenolic tannin bound to and cross-linking elastin of the tissue.

Adkisson and Asculai, et al. fail to disclose or suggest additional limitations of the claims as well. For instance, even were Adkisson and Asculai, et al. to be combined as suggested in the Office Action, the combined references would still fail to disclose or suggest an implantable tissue including a residue of a phenolic tannin cross-linking agent bound to and crosslinking elastin of the tissue and also including a residue of a glutaraldehyde cross-linking agent bound to and cross-linking collagen of the fixed tissue as is found in claim 24.

In addition, even if combined, the combined references would still fail to disclose or suggest an implantable fixed tissue including both a residue of a phenolic tannin cross-linking agent bound to and cross-linking elastin of the fixed tissue, and also including a residue of an aldehyde cross-linking agent bound to and cross-linking collagen of the fixed tissue, as is found in claim 48.

For at least these reasons, Applicants respectfully submit that claims 20-21, 23-24, and 28 patentably define over the cited references and request withdrawal of the rejection.

As a final matter, Applicants respectfully request rejoinder of withdrawn claims 30-39 and 47 to the pending application. The claims are related as

subcombination/combination claims. Such claims require two-way distinctness for maintenance of a restriction requirement. Specifically, the inventions are distinct if it can be shown that a combination as claimed (A) does not require the particulars of the subcombination as claimed for patentability and (B) the subcombination can be shown to have utility either by itself or in another materially different combination (MPEP §806.05(c)). In the present instance, Applicants submit that the combination as claimed in independent claim 30 requires the implantable fixed tissue as claimed in the subcombination of independent claim 20. Accordingly, the two-way distinctness requirement has not been met, and Applicants request rejoinder of the claims.

It is believed that the present application is in complete condition for allowance and favorable action is therefore requested. Examiner Kumar is invited and encouraged to telephone the undersigned at her convenience should there be any questions with regard to this application.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,
DORITY & MANNING, P.A.

8/9/07

BY: 

Christina L. Mangelsén, Patent Agent
Registration No. 50,244
P.O. Box 1449
Greenville, SC 29602-1449
(864) 271-1592
(864) 233-7324 - Fax